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Science Advisers Suggest Minor Changes To EPA's TCE Risk Analysis

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EPA's Science Advisory Board (SAB) is recommending clarifications and minor changes to the agency's assessment of the risks posed by the ubiquitous solvent trichloroethylene (TCE), a widespread groundwater contaminant.

The SAB executive committee approved a report reviewing the draft risk assessment prepared by an SAB work group -- pending some editorial changes -- during a Dec. 15 conference call. The approved draft of the report supports EPA's classification of TCE as "carcinogenic to humans" as well as its estimates of cancer risk.

However, the advisers are urging EPA to reconsider the endpoints used for its non-cancer risk estimate, which was based on renal effects. The advisers did not believe that the studies showing those effects are of sufficient quality to calculate risk estimates, said Deborah Cory-Slechta, the work group's chair.

"We didn't agree with the use of the three studies of renal effects," she said, pointing to uncertainties in the differences between animal and human metabolism of the chemical. "There were limitations in all three studies, including . . . mortality that made derivation of any kind of value difficult."

The advisers are instead recommending that EPA focus on three other studies it considered but ultimately rejected as the best basis for non-cancer risk estimates: immune system studies and a controversial study of fetal cardiac malformations that could make EPA's risk estimate more stringent.

The report also urges EPA to consider French cancer rates, rather than American ones when it weighs cancer risks, since the agency's cancer risk estimates are based on a study of French workers.

The advisers effectively rejected industry's arguments to delay the risk assessment. Industry argued, prior to the executive panel's deliberations, that the risk assessment "is not ready for release," according to Caffey Norman, an attorney working for the Halogenated Solvents Industry Alliance (HSIA). Norman urged SAB to recommend EPA perform extensive revisions to the assessment. He also argued that "scientific integrity requires [SAB] to address" a 2009 report from the National Academy of Sciences (NAS), *Contaminated Water Supplies at Camp Lejeune, Assessing Potential Health Effects*. TCE was among a mixture of chemicals that contaminated drinking water at Camp Lejeune Marine Corps Base, NC. Norman argued that the NAS report does not classify TCE as a human carcinogen, but instead describes "limited or suggested evidence of an association" between TCE and human cancer.

Asked about the NAS report, Cory-Slechta disagreed that the latest SAB report is inconsistent with it. "I was a member of that [NAS] panel. What we review was very different," she said. "We were reviewing completely different documents, the charge was different, the documents were different. These are really apples and oranges."

Paul Dugard, a toxicologist with HSIA, argued that EPA's cancer risk estimate suggests the agency put more weight on the French worker study than it should have done, which he argued was "not sufficiently robust" to form the basis of the agency's calculations.

The report does raise questions about the agency's use of age dependent adjustment factors (ADAFs), extra safety factors applied to chemicals thought to pose specific cancer risks to children. These factors were not included in the original French study -- which assumes one lifetime relative risk of cancer -- that is the basis of the cancer assessment. The advisers recommend that EPA calculate "estimated drinking water concentrations for specified lifetime cancer risk levels (10-4, 10-5, 10-6), using representative drinking water intakes for various age groups."

And they recommend that EPA add "a discussion of the perceived conflict between the use of ADAFs and the assumptions underlying the life table analysis of the [French] data."

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